EU Regulations on Food Supplements, Health foods, herbal medicines

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Summary
The European Union has taken steps to harmonize the regulation of nutritional supplements, health foods and herbal medicines across the EU. Though some diverging regulations amongst Member States result in challenges for companies in the sector, the harmonization of EU rules overall provides an opportunity for US exporters entering the single market of 27 EU member states. This report provides an overview of the various pieces of legislation in this sector.

Introduction
In an effort to harmonize the internal EU market for food supplements and similar products the European Union has adopted some key pieces of legislation. This report will provide a brief overview of the market for nutrition products in the EU and a look at the European Food Safety Authority (EFSA). This is followed by a summary of each piece of legislation related to:

- Food supplements
- Nutritional and functional claims
- Novel Foods
- Dietetic foods
- Traditional herbal medicinal products
- Fortified foods
- Food labeling

The Market for Nutrition Products in Europe
In the European Union (EU), the vitamins and dietary supplements market totaled nearly €7 billion in 2009. According to the European Commission's 2008 Working Document, food supplement products containing vitamins and minerals have a 50% share of the market. Euromonitor International's 2009 research revealed that supplements taken to address digestive health, the immune system, joint health, beauty and heart health were the most popular products in Western Europe, accounting for more than 55% of value sales of all dietary supplements. A similar finding also applies to Eastern Europe.

The number of substances other than vitamins and minerals used in food supplements on the European market is estimated to be over 400. Some of the most commercially significant include fish oils, probiotics and herbal ingredients. Other substances include amino acids, enzymes, prebiotics, essential fatty acids, botanicals, other substances like lycopenes, and glucosamine.

Another issue to note is that significant national variations exist. For example, fish oils constitute over 50% of the market of other substances in Denmark, but under 3% in Spain and in Italy. Probiotics account for 44% of the market in Italy and only 0.3% in Denmark. Herbal products (ginkgo, ginseng, St John's Wort, echinacea and garlic) make up 75% of the market in the Netherlands, 40% in France, and under 5% in Italy.

Until relatively recently, the market for vitamins and dietary supplements was underdeveloped in Eastern Europe but in the last couple of years, the demand for these products has grown very quickly, due to increasing disposable income of Eastern European countries and their growing concern for a healthy lifestyle and illness prevention.

The channels for distribution vary by country, with the majority of sales occurring in pharmacies. In the UK market, grocery stores and pharmacy chains are prevalent, while independent pharmacies dominate the markets in France, Germany, Denmark and Italy. Some other retail outlets including supermarkets are beginning to be developed in some countries such as Italy. Drugstores are gaining ground in countries such as Austria. Health food stores are also becoming more popular for example in Denmark.

Source: Euromonitor, European Commission

The European Food Safety Authority (EFSA)

The European Food Safety Authority (EFSA) was set up in January 2002 as an independent source of scientific advice that produces opinions which then are used by the European Commission to adopt legislation. Most relevant for companies in the food supplements sector, EFSA has been asked by the European Commission to evaluate proposals for the addition of vitamins and minerals to the Food Supplements Directive and to evaluate nutrition and health claims. EFSA has also worked with the European Commission on assessing how to establish maximum limits for vitamins and minerals in food supplements and fortified foods and provided opinions on substances other than vitamins and minerals. EFSA works in close collaboration with national authorities and in open consultation with its stakeholders.

Food Supplements Directive

The Food Supplements Directive (FSD) Directive 2002/46/EC, establishes a definition for food supplements, establishes a list of allowable vitamins and minerals, and sets labeling requirements. The Directive calls for the establishment of harmonized minimum and maximum dosage amounts however this has yet to be done and remains a competence of EU member states. Also, substances other than vitamins and minerals are not directly covered by the directive and rules regulating these substances are still governed by individual EU Member States.

Definition

Food supplements are "foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological function, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities."

Scope

The scope of the FSD includes vitamins and minerals. Rules for nutrients other than vitamins and minerals should be developed in the future and for now are governed by Member State legislation.

List of allowable vitamins and minerals

The Directive establishes a positive list of allowable vitamins and minerals and their associated forms to be included in food supplements. The list as amended by Regulation

1170/2009 includes 13 vitamins with 45 allowable sources and 17 minerals with a total of 136 allowable sources.

Addition of substances
Additional vitamin and mineral substances may be considered for inclusion in the lists following the evaluation of an appropriate scientific dossier concerning the safety and bioavailability of the individual substance by EFSA. Companies wishing to market a substance not included in the permitted list need to submit an application to the European Commission. Guidance document

Labeling
The directive sets forth labeling requirements for foodstuffs to include:

- the names of the categories of the nutrients or substances that characterize the product or an indication of the nature of those nutrients or substances;
- the portion of the product recommended for daily consumption and a warning of the risks to health if this is exceeded;
- a declaration to the effect that the supplement is not a substitute for a varied diet;
- a warning to the effect that the product should be stored out of the reach of young children.

The labeling of food supplements must not contain:

- any statement attributing to the product properties of preventing, treating or curing a human disease;
- any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

Minimum and maximum levels
The Directive calls for the establishment of minimum dosage amounts for a product to be considered a nutritional supplement as well as upper safe limits to protect the consumer. However the European Commission and the European Food Safety Authority have not made progress on establishing these limits and this competence remains up to the Member states.

Substances other than vitamins and minerals
The European Commission prepared a report on the use of substances other than vitamins and minerals in food supplements and concluded that it was not feasible or necessary to lay down specific EU rules, given already existing EU legislation that regulate their use and member state legislation which should be mutually recognized throughout the EU.

Natural ingredients
The scope of the directive encompasses all food supplements, it does not cover the use of natural ingredients in food supplements. Accordingly, a natural food source of vitamins or minerals (eg cod liver oil) may be included in nutritional supplements as an ingredient even though the substance "cod liver oil" is not included in any of the annexes to the directive.

Nutrition and Health Claims
A very important piece of legislation for the food supplements sector is the regulation on nutrition and health claims Regulation 1924/2006 which sets EU-wide conditions for the use of nutrition and health claims.

A nutritional claim suggests a food has beneficial nutritional properties, such as "low fat", "no added sugar" and "high in fiber". A health claim is a statement that suggests a relationship between food and health for instance that a food can "help lower cholesterol", "help reinforce the body's natural defenses" or "enhance learning ability".

The regulation applies to any food or drink product produced for human consumption that is marketed on the EU market.

Nutrition and health claims will only be allowed on food labels if they are included in one of the EU positive lists. Food products carrying claims must comply with the provisions of nutritional labeling directive 90/496/EC and its amended version to come into effect in 2011.

Nutrition claims referring to the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium have been adopted and are listed in the Commission's register.

Health claims already adopted by the Commission are listed in its register. The Commission is scheduled to adopt a new list of functional health claims for all substances other than botanicals by 2011. So far EFSA has mostly accepted claims for vitamins, some minerals, omega-3s and sterols/stanols, but has rejected many hundreds of claims especially for pre- and probiotics.

Health claims regarding botanicals will be considered after 2011. Disease risk reduction claims and claims referring to the health and development of children require an authorization on a case-by-case basis, following the submission of a scientific dossier to EFSA. Health claims based on new scientific data will have to be submitted to EFSA for evaluation but a simplified authorization procedure has been established.

A guidance document on how companies can apply for health claim authorizations can be downloaded from EFSA's website.

Botanicals
Food supplements from botanicals and derived preparations made from plants, algae, fungi or lichens have become widely available on the EU market. Examples include ginkgo, garlic, St. John's Wort and ginseng. Such products are typically labeled as natural foods and a variety of claims are made regarding possible health benefits. They can be bought over the counter in pharmacies, supermarkets, specialist shops and via the Internet.

There is currently no EU legislation specifically for botanicals other than the general EU food legislation Regulation 178/2002. EFSA is currently discussing what the permitted types of botanical ingredients and how their safety should be assessed. EFSA is also discussing which health claims should be permitted and on which levels and types of evidence they should be based.

Novel Foods
Food supplements also need to comply with the EU rules on novel foods. The Novel Foods Regulation lays down rules for novel foods that were not used before 1997. In order for food and supplements containing novel ingredients to be allowed on the EU market, an application for authorization must be submitted to the competent authorities. The EU is currently revising the rules on novel foods which will cover foods produced by new techniques/technologies such as cloning, nanotechnology and foods with a history of safe use in other countries such as noni juice. The proposal is still under discussion and could be adopted in 2011. More information can be found on the Commission's website.

Dietetic/ PARNUTS Foods

There are a series of directives related to foodstuffs intended to satisfy particular nutritional requirements of specific groups of the populations. Directive 2009/39/EC sets out a framework of rules for the composition, marketing and labeling requirements of these "dietetic foods". Regulation 953/2009 lists the substances (vitamins, minerals and amino acids) that may be added for specific nutritional purposes in foodstuffs for particular nutritional uses.

The framework directive lists the following four groups of dietary foods for which specific rules are to be set out:

- Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children.
- Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction.
- Directive 2006/141/EC on infant formula and follow-on formula, amended by Regulation 1243/2008 as regards compositional requirements for certain infant formulae.
- Directive 1999/21/EC on dietary foods for special medical purposes.

Regulation 41/2009 lays down new EU harmonized rules for the composition and labeling of foodstuffs suitable for people who are intolerant to gluten. This regulation, applicable as of January 1, 2012, sets conditions for the use of the terms "very low gluten" and "gluten-free".

Specific directives on foods and beverages for sports people or on foods intended for diabetics are still subject to Member State legislation.

Traditional Herbal medicines

All medicinal products, including herbal medicinal products, need a marketing authorization to be placed on the EU market. The Herbal Directive 2004/24/EC was adopted to facilitate the placing on the EU market of traditional herbal medicinal products through a simplified procedure. As from May 1, 2011, applicants must submit the corresponding application to the competent authorities in the Member States where they want to market.

For registration as a traditional herbal medicinal product, the applicant must provide sufficient evidence of the medicinal use of the product throughout a period of at least 30 years, including at least 15 years in the European Union**.**

The European Medicines Agency (EMA) does not have a role in the registration of traditional herbal medicinal products. This means that applications for registration need to be submitted in each Member State where the product is to be marketed. These applications are handled by the competent authority in each Member State. The European Commission shall establish an EU list of herbal preparations or herbal substances so that Member States shall recognize registration of traditional herbal medicinal products granted by another Member State whenever it is based on the EU list.

Herbal products may be classified and placed on the market as food provided that they do not fulfill the definition of medicinal products and that they comply with the applicable food law. In particular, herbal products marketed in the form of food supplements should comply with Directive 2002/46/EC on food supplements and Regulation 1924/2006 on nutrition and health claims made on foods.

After May 1, 2011 all unlicensed herbal medicinal products must either be marketed as medicines, or they must be 'withdrawn' from the market. They could be launched correctly

labeled as food supplements, carrying no claims unless those claims have been approved according to the Nutrition and Health Claims Regulation.

Fortified Foods
European Regulation 1925/2006 establishes common rules concerning the addition of vitamins, minerals and certain other substances to foods. This regulation harmonizes the different rules in force in Member States by establishing a list of vitamins and minerals which are authorized to be added to foods. Only vitamins and minerals from these positive lists can be used, though certain derogations can be obtained until January 19, 2014. The regulation sets minimum amounts based on the notion of "significant amount" as defined in the Annex to Council Directive 90/496/EEC on nutrition labeling.

Food labeling
Directive 2000/13/EC on the Labeling, Presentation and Advertising of Foodstuffs is the main EU directive on food labeling. It ensures that the consumer gets all the essential information regarding the composition of a product, its manufacturer, the method of storage and preparation. Directive 90/496/EEC on Nutrition Labeling for Foodstuffs lays down harmonized rules on the presentation and content of nutritional information for pre-packed foods. But the inclusion of nutrition information is voluntary unless a nutrition-related claim is made on the package.

In January 2008, the Commission proposed a Regulation on Information to Consumers on foodstuffs that would make nutrition declaration compulsory. The energy value and the quantities of some nutrients (fat, saturates, carbohydrates, protein, sugars and salt) would have to be indicated on the packaging. In general terms, they would be expressed per 100g or per 100ml, but could also be indicated as a percentage of reference intakes. Discussions will continue in 2011.

Weblinks to member states reports:

Italy
http://www.buyusainfo.net/docs/x_8534182.pdf
Denmark
http://www.buyusainfo.net/docs/x_4357941.pdf
Hungary
http://www.buyusainfo.net/docs/x_8058842.pdf
Austria
http://www.buyusainfo.net/docs/x_9348761.pdf
Germany
http://www.buyusainfo.net/docs/x_9692057.pdf

USDA Food and Agricultural Import Regulations and Standards EU-27 2010 report:
http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20and%20Agricultural%20Import%20Regulations%20and%20Standards%20-%20Narrative_Brussels%20USEU_EU-27_12-21-2010.pdf

European Commission Directorate General for Health and Consumers
http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm

European Food Safety Authority
http://www.efsa.europa.eu/

For More Information:
The U.S. Commercial Service at the U.S. Mission to the European Union is located at Boulevard du Regent 27, Brussels BE-1000, Belgium, and can be contacted via e-mail at: brussels.ec.office.box@trade.gov; or by visiting the website: www.buyusa.gov/europeanunion.

One can locate the nearest U.S. Export Assistance Center or Commercial Service offices throughout Europe by visiting www.buyusa.gov and www.buyusa.gov/europe.